UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	MDL No. 09-2100 Civil Action No. _____
This document relates to:	**COMPLAINT AND DEMAND FOR JURY TRIAL**
SARAH SAMET, Plaintiff, v. BAYER CORPORATION; BAYER PHARMACEUTICALS CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC; BAYER HEALTHCARE, LLC; BAYER HEALTHCARE AG; BERLEX LABORATORIES INTERNATIONAL, INC.; and, BERLEX, INC. Defendants.	

Plaintiff, by and through counsel, and for her Complaint against Defendants, alleges as follows:

PARTIES AND JURISDICTION

1. Plaintiff Sarah Samet is a resident and citizen of San Jose, California, located in San Jose County.

2. Upon information and belief, Plaintiff Sarah Samet was prescribed and ingested Yasmin. After using Yasmin, Plaintiff Sarah Samet suffered from a gallbladder injury and underwent removal of her gallbladder on or about February 6, 2009.

3. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

4. Upon information and belief, Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

5. Upon information and belief, Defendant Bayer Pharmaceuticals Corporation is a Delaware corporation, with its principal place of business located in the state of Connecticut. On information and belief, as of January 1, 2008, Defendant Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare Pharmaceuticals, Inc. Defendant Bayer Pharmaceuticals Corporation was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Bayer Pharmaceuticals Corporation conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

6. Upon information and belief, Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer

Healthcare and Berlex Laboratories International, Inc.. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

7. Upon information and belief, Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories International, Inc.. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

8. Upon information and belief, Defendant Bayer Healthcare AG is a company domiciled in Germany and is the parent/ holding company of, and exercises dominion and control over, Defendants Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories International, Inc., and Berlex, Inc. Defendant Bayer Healthcare AG was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its

products, including the prescription drug Yasmin. At all relevant times, Defendant Bayer Healthcare AG conducted regular and sustained business within the United State of America, and Minnesota in particular, by selling and distributing its products in Minnesota.

9. Upon information and belief, Defendant Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc.. Defendant Berlex Laboratories International, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Berlex Laboratories International, Inc. conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

10. Defendant Berlex, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Defendant Berlex, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yasmin. At all relevant times, Defendant Berlex, Inc. conducted regular and sustained business in Minnesota by selling and distributing its products in Minnesota.

11. Defendants Bayer Corporation, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Healthcare AG, Berlex

Laboratories International, Inc., and Berlex, Inc. are collectively referred to herein as "Bayer" or "Defendants."

JURISDICTION

12. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

13. Venue in this Court is proper in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell and market Yasmin within Minnesota and nationwide.

FACTUAL BACKGROUND

Nature of the Case

14. Plaintiff brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yasmin (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, Plaintiff suffered from a gallbladder injury and underwent removal of her gallbladder on or about February 6, 2009 as a direct result of her use of Yasmin.

Bayer's Combined Oral Contraceptives – Yasmin and Yaz

15. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

16. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

17. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

18. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin. As detailed below, this combination of drugs, and DRSP alone, significantly increase the risk for hyperkalemia. As a result, users, such as Plaintiff in this case, have been subjected to significant health risks, including blood clots (deep vein thrombosis) (DVT), pulmonary embolism (PE), stroke (cerebrovascular accidents), heart attack (myocardial infarction), gallbladder disease, gallbladder removal (cholecystectomy), kidney failure or renal failure, pancreatitis and in some cases, death.

19. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

20. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

21. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

22. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

23. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.

24. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

25. One possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

26. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

27. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can

then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

28. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

29. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

30. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

31. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.

32. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

33. Some deaths reported occurred in women as young as 17 years old.

34. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

Over-Promotion of Yasmin and Yaz

35. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

36. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

37. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories International, Inc. promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

38. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

39. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

40. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

41. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

42. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone … which can lead to

hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

43. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

44. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

45. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yasmin advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yasmin and Resulting Injuries

46. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin, Plaintiff Sarah Samet's medical provider prescribed and Plaintiff began using Yasmin in or around August, 2007. As a direct result of her use of Yasmin, Plaintiff suffered from a gallbladder injury and underwent removal of her gallbladder on or about February 6, 2009.

47. As a direct and proximate result of using Yasmin, Plaintiff suffered the injuries described above.

48. Prior to February, 2009, Defendants knew or should have known that use of Yasmin created a higher risk significant injuries including blood clots (deep vein thrombosis) (DVT), pulmonary embolism (PE), stroke (cerebrovascular accidents), heart attack (myocardial infarction), gallbladder disease, gallbladder removal (cholecystectomy), kidney failure or renal failure, pancreatitis and in some cases, death than other oral contraceptives on the market,

including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

49. Therefore, at the time Plaintiff used Yasmin, Defendants knew or should have known that the use of Yasmin created an increased risk to consumers of serious personal injury, including blood clots (deep vein thrombosis) (DVT), pulmonary embolism (PE), stroke (cerebrovascular accidents), heart attack (myocardial infarction), gallbladder disease, gallbladder removal (cholecystectomy), kidney failure or renal failure, pancreatitis and in some cases, death.

50. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin, Defendants failed to warn Plaintiff and/or her health care providers of said serious risks before she used the product.

51. Had Plaintiff and/or her heath care providers known the risks and dangers associated with Yasmin, she would not have used Yasmin and would not have suffered from a gallbladder injury and removal of her gallbladder.

52. At the time of her injuries on or about February 6, 2009, Plaintiff was unaware that Yasmin was defective and presented a significantly higher risk of injuries, such as gallbladder injuries.

53. As a direct and proximate result of her use of Yasmin, Plaintiff suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her gallbladder injury and removal of her gallbladder.

54. As a direct and proximate result of her use of Yasmin, Plaintiff has suffered and will continue to suffer pecuniary losses.

FIRST CAUSE OF ACTION
Strict Products Liability
Defective Manufacturing

55. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

56. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin.

57. The Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

58. The Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when it left the hands of Defendants in that it deviated from product specifications such that it was unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

59. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and noneconomic damages, and will continue to suffer such harm, damages, and economic loss in the future.

SECOND CAUSE OF ACTION
Strict Products Liability
Design Defect

60. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

61. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yasmin.

62. The Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

63. The Yasmin birth control pills manufactured and supplied by Defendants were defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

64. The foreseeable risks associated with the design or formulation of the Yasmin birth control pills, include, but are not limited to, the fact that the design or formulation of Yasmin is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

65. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and noneconomic damages, and will continue to suffer such harm, damages, and economic loss in the future.

THIRD CAUSE OF ACTION
Strict Products Liability
Defect Due to Inadequate Warning

66. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

67. The Yasmin birth control pills manufactured and supplied by Defendants were defective due to inadequate warnings or instructions and were unreasonably dangerous to the

ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and failed to adequately warn consumers and/or their health care providers of such risks.

68. The Yasmin birth control pills manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction and were unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yasmin, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

69. As a direct and proximate result of Plaintiff's use of Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and noneconomic damages, and will continue to suffer such harm, damages, and economic loss in the future.

FOURTH CAUSE OF ACTION
Negligence

70. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

71. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Yasmin into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

72. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yasmin into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

73. Defendants also failed to exercise ordinary care in the labeling of Yasmin and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Yasmin.

74. Despite the fact that Defendants knew or should have known that Yasmin posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Yasmin for use by consumers.

75. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

76. As a direct and proximate result of Defendants' negligence, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

FIFTH CAUSE OF ACTION
Negligent Misrepresentation

77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

78. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yasmin and made representations to Plaintiff and her physician regarding the character or quality of Yasmin for guidance in their decision to select Yasmin.

79. Specifically, Defendants represented that their product was just as safe or safer, and just as effective or more effective, than other birth control products on the market.

80. Defendants' representations regarding the character or quality of Yasmin were untrue.

81. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yasmin created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

82. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safer and more effective than other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

83. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and her physician.

84. Plaintiff and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff reasonably relied upon Defendants' representations to her and/or her health care providers that Yasmin was safer than other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

85. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION
Breach of Express Warranty

86. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

87. Defendants expressly warranted that Yasmin was safe and well accepted by users.

88. The combination oral contraceptive Yasmin does not conform to these express representations because Yasmin is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants.

89. Plaintiff did rely on the express warranties of the Defendants herein.

90. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Yasmin in recommending, prescribing, and/or dispensing Yasmin.

91. The Defendants herein breached the aforesaid express warranties, as their drug Yasmin was defective.

92. Defendants expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that Yasmin was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of combination oral contraceptives, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

93. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Yasmin was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

94. As a result of the foregoing acts and/or omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder

disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

95. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

96. As a direct and proximate result of Defendants' breach of express warranties, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

SEVENTH CAUSE OF ACTION
Breach of Implied Warranty

97. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

98. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Yasmin and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Yasmin, for use in contraception.

99. At the time Defendants marketed, sold, and distributed Yasmin for use by Plaintiff, Defendants knew of the use for which Yasmin was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

100. The Defendants impliedly represented and warranted to the users of Yasmin and their physicians, healthcare providers, and/or the FDA that Yasmin was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

101. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Yasmin was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

102. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

103. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Yasmin was of merchantable quality and safe and fit for its intended use.

104. The combination oral contraceptive Yasmin was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

105. The Defendants herein breached the aforesaid implied warranties, as their drug Yasmin was not fit for its intended purposes and uses.

106. As a result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events,

including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

107. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

108. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

EIGHTH CAUSE OF ACTION
Fraudulent Misrepresentation

109. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

110. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff, and/or the FDA, and the public in general, that said product, Yasmin, had been tested and was found to be safe and/or effective for contraceptive purposes.

111. That representations made by Defendants were, in fact, false.

112. When said representations were made by Defendants, they knew those representations to be false and willfully, wantonly and recklessly disregarded whether the representations were true.

113. These representations were made by said Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Yasmin, for use as a means of birth control, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

114. At the time the aforesaid representations were made by the Defendants and, at the time Plaintiff used Yasmin, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

115. In reliance upon said representations, Plaintiff was induced to and did use Yasmin, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

116. Said Defendants knew and were aware or should have been aware that Yasmin had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

117. Defendants knew or should have known that Yasmin had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

118. Defendants brought Yasmin to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

119. As a result of the foregoing acts and omissions, Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

120. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

121. As a direct and proximate result of Defendants' fraud and/or fraudulent misrepresentations or omissions, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

NINTH CAUSE OF ACTION
Fraudulent Concealment

122. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

123. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Yasmin for its intended use.

124. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the levels of estrogen delivered by Yasmin.

125. Defendants knew or were reckless in not knowing that its representations were false.

126. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Yasmin was not as safe as other forms of contraception;

(b) that the risks of adverse events with Yasmin were higher than those with other forms of birth control, including but not limited to other forms of oral contraception;

(c) that the risks of adverse events with Yasmin were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in Yasmin, in addition to and above and beyond those associated with other forms of oral birth control methods;

(e) that Yasmin was defective, and that it caused dangerous side effects, including but not limited to higher incidence of stroke, transient ischemic attack ("TIA"), embolisms, blood clots, heart attacks, coma, and death, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of birth control, including but not limited to oral birth control;

(f) that patients needed to be monitored more regularly than normal while using Yasmin;

(g) that Yasmin was manufactured negligently;

(h) that Yasmin was manufactured defectively;

(i) that Yasmin was manufactured improperly;

(j) that Yasmin was designed negligently;

(k) that Yasmin was designed defectively; and

(l) that Yasmin was designed improperly.

127. Defendants were under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Yasmin, including but not limited to the heightened risks of an adverse cardiovascular event, such as a heart arrhythmia, myocardial infarction or sudden death.

128. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Yasmin, including Plaintiff, in particular.

129. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Yasmin was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and her physicians, hospitals and healthcare providers into reliance, continued use of Yasmin, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Yasmin and/or use the product.

130. Defendants knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin, as set forth herein.

131. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

132. As a result of the foregoing acts and omissions Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder

disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

133. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

134. As a direct and proximate result of Defendants' fraud and/or fraudulent concealment or omissions, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

TENTH CAUSE OF ACTION
Fraud and Deceit

135. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

136. Defendants conducted research and used Yasmin as part of their research.

137. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Yasmin was safe and effective for use as a means of providing birth control.

138. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including Plaintiff.

139. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and Plaintiff, as well as her respective healthcare providers and/or the FDA.

140. The information distributed to the public, the FDA, and Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

141. The information distributed to the public, the FDA, and Plaintiff by Defendants intentionally included representations that Defendants' drug Yasmin was safe and effective for use as a form of birth control.

142. The information distributed to the public, the FDA, and Plaintiff by Defendants intentionally included representations that Defendants' drug Yasmin carried the same risks, hazards, and/or dangers as other forms of combination oral birth contraception.

143. The information distributed to the public, the FDA, and Plaintiff by Defendants intentionally included representations that Defendants' drug Yasmin was more effective in treating the symptoms of premenstrual dysphoric disorder and moderate acne than other forms of combination oral contraceptives, encouraging the use of Yasmin in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risk associated with Yasmin.

144. The information distributed to the public, the FDA, and Plaintiff by Defendants intentionally included false representations that Yasmin was not injurious to the health and/or safety of its intended users.

145. The information distributed to the public, the FDA, and Plaintiff by Defendants intentionally included false representations that Yasmin was as potentially injurious to the health and/or safety of its intended as other forms of oral forms combination oral contraceptives.

146. These representations were all false and misleading.

147. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Yasmin was not safe as a means of contraception and/or was not as safe as other means of contraction, including but not limited to other forms of combination oral contraceptives.

148. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and Plaintiff, regarding the safety of Yasmin, specifically but not limited to Yasmin not having dangerous and serious health and/or safety concerns.

149. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession and Plaintiff, regarding the safety of Yasmin, specifically but not limited to Yasmin being as safe a means of birth control as other forms of combination oral contraception.

150. Defendants intentionally made material misrepresentations to deceive and defraud the public, the FDA, and/or Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or Plaintiff, to falsely ensure the quality and fitness for use of Yasmin and induce the public, and/or Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Yasmin.

151. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that Yasmin was fit and safe for use as birth control.

152. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that Yasmin was fit and safe for use as birth control and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of combination oral contraceptives.

153. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and Plaintiff that Yasmin did not present serious health and/or safety risks.

154. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and Plaintiff that Yasmin did not present health and/or safety risks greater than other oral forms of contraception.

155. These representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

156. These representations and others, made by Defendants, were made with the intention of deceiving and defrauding Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Yasmin.

157. Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Yasmin to the public at large, Plaintiff in particular, for the

purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of oral contraception.

158. Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Yasmin by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Yasmin.

159. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Yasmin and/or that their respective healthcare providers would dispense, prescribe, and/or recommend the same.

160. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including Plaintiff, as well as her respective healthcare professionals, would rely upon the information being disseminated.

161. Defendants utilized direct-to-consumer adverting to market, promote, and/or advertise Yasmin.

162. Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of birth control and were thereby induced to purchase, use and rely on Defendants' drug Yasmin.

163. At the time the representations were made, Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Yasmin.

164. Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could Plaintiff with reasonable diligence have discovered the true facts.

165. Had Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Yasmin, Plaintiff would not have purchased, used and/or relied on Defendants' drug Yasmin.

166. The Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on Plaintiff.

167. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including, stroke, transient ischemic attack, blood clots, embolisms, kidney and gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a future of high risk pregnancies, any and all life complications created by Plaintiff's inability to use any form of prescription contraception for the duration of her life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

168. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

169. As a direct and proximate result of Defendants' fraud and/or deceit, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to non-economic damages in excess of $75,000.00;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Attorneys' fees, expenses, and costs of this action;

4. Such further relief as this Court deems necessary, just, and proper.

PLAINTIFF HEREBY DEMANDS A JURY TRIAL.

Dated: 2/15, 2010.

Respectfully submitted,

GOLDENBERG & JOHNSON, PLLC

By _____
Michael K. Johnson (#258696)
Lucia J. W. McLaren (#388088)
33 South Sixth Street, Suite 4530
Minneapolis, Minnesota 55402
(612) 333-4662